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10/042,312	01/11/2002	Kanji Yahiro	2001_1892A	4407

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,312

Applicant(s)

YAHIRO, KANJI

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/13/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Applicant's amendments and remarks, filed 4/13/04, are acknowledged. Amended claims 1-2, 4-7, 9-12, and 14-15 are acknowledged.

Applicant's arguments, filed 4/13/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-15 are herein under examination.

Claim Objections

Claim 15 is objected to because of the following minor informality: Line 3 of instant claim 15 recites a "(2)" while it is not preceded by a (1). Appropriate correction is requested. This objection is necessitated by amendment.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 5, 7, 10, 12, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 5, 7, 10, 12, and 15 have amended portions that include two instances separated by “(i)” and “(ii)” which be interpreted to mean that the limitation is recited to have at least one of the “(i)” subject matter and one of the “(ii)” subject matter. For the subject matter in instant claims 2, 7, and 12, for example, the specification mentions (page 8, lines 7-9) “the number of cells in the measuring area or the surface area” which does not require both conditions. The originally filed claims 2, 7, and 12 recite “at least one of a number of the cell and an area of the cell” which is broad and subject to numerous interpretations. Attempting to narrow down the subject matter to require both when there is not specific support for this concept results in the new amended portion to be considered NEW MATTER. A similar issue holds for amended claims 5, 10, and 15 regarding the “length or area” support in the specification of page 8, line 13 where only one characteristic is numerically obtained. Meanwhile the original claims stated “at least one of a length and an area” which is too broad to provide specific support that both “(i)” and “(ii)” limitations are required as now stated in amended claims 5, 10, and 15.

Claims 2, 5, 7, 10, 12, and 15 have been amended to recite the term “entire” which does not appear to have adequate support in the specification, claims, or figures as originally filed. While page 7, lines 20-23, recites a sample area or the range of the sum of areas, it does not provide support that this area is the entire area of the number of cells, as now stated in amended claims 2, 7, and 12. While page 8, line 13, states “the length or area of linear structure”, this passage does not provide support for the entire area of the linear structure as now stated in amended claims 5, 10, and 15. Because the introduction of the term “entire” does not appear to

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have adequate written basis, amended claims 2, 5, 7, 10, 12, and 15 with this new subject matter are rejected as containing NEW MATTER. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 10, and 15 recite the phrase “a length” which is vague and indefinite. It is unclear if this length is the length of anything or if this length is intended to be a length of the linear structure. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. This rejection is necessitated by amendment.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-4, 6-9, and 11-14 is necessitated by amendment under 35 U.S.C. 102(b) as being anticipated by Wilhelm et al. (P/N 5,715,327).

Wilhelm et al. disclose a method performed on an automated microscope system and evaluation apparatus for determining whether a slide containing a biological sample is suitable for processing (abstract). Wilhelm et al. disclose taking an image of the biological sample on the slide, processing the slide, determining whether the slide is suitable based on parameters, and

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whether a threshold (predetermined condition) has been exceeded (Figure 2). Wilhelm et al. disclose the biological sample includes a cell and the parameters (predetermined conditions) including cell ratios (cell numbers) and rings around the cell nuclei (area of the cell), mean nuclei stain, mean cytoplasm stain, and mean contrast between nuclei and cytoplasm (representing entire cell area) (abstract, Figure 4, and col. 1, lines 35-47) as stated in instant claims 2, 7, and 12. In Figure 1A, Wilhelm et al. disclose a calibration slide 524 (reference image). Wilhelm et al. disclose detecting intermediate cell ratios and reference cell ratios (col. 2, line 22) which are reasonably interpreted as a reference image compared to the test slide in the measuring area, as stated in instant claims 3, 8, and 13. Wilhelm et al. disclose a slide suitability score which results from analyses applied to measurements of the slide's characteristics and an automated cytology system's effectiveness (col. 1, lines 10-12), which represent predetermined values resulting from a comparison between the test slide image and the reference slide image, as stated in instant claims 4, 9, and 14.

Wilhelm et al. disclose the apparatus includes an imaging system, a motion control system (measuring area changing unit), an image processing system (condition determining unit and digitizing unit), a central processing system, and a workstation (col. 3, lines 49-52 and col. 4, lines 23-26 and 37-42). Wilhelm et al. disclose the motor drivers position the slide under the optics (col. 4, line 9) and that measurements are taken on requested fields of view (col. 1, lines 17-18) so that the motor driver is reasonably interpreted to be a measuring changing unit that changes the measuring area, as stated in instant claim 1. Wilhelm et al. disclose a hard disk (col. 4, line 17) that represents a storage medium, as stated in instant claims 11-15. Wilhelm et al. disclose the processes are implemented in software (computer program for executing a digital

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processor) (col. 4, lines 33-37). Wilhelm et al. disclose a central computer that controls the microscope and processor to acquire and digitize images from the microscope (col. 4, lines 23-26). The computer controls the microscope stage to position the specimen where one to fifteen field of view processors receive images (col. 4, lines 28-32). Wilhelm et al. disclose the flatness of the slide may be checked prior to slide suitability testing (col. 4, lines 23-32) which represents a determination if the slide conforms to a predetermined condition, as stated in instant claim 1. The processor computes a suitability score that indicates whether a slide has passed or failed (condition pass/fail determining unit) in any one of the thirteen suitability tests, as stated in instant claim 1. Wilhelm et al. disclose creating an image of the slide, measuring a suitability parameter, and then checking if the parameter exceeds a predetermined threshold (col. 5, lines 28-34) which represents a condition being previously set and judging whether the measuring area (image) conforms to the condition, as stated in instant claims 6 and 11. Wilhelm et al. disclose a slide must pass all tests in order to be suitable for reporting results (col. 4, lines 39-40) which represents acquisition of data judged to conform to the condition, as stated in claims 6 and 11. Therefore, if a slide does not pass all tests, then processing is considered unsuitable and result processing must cease (col. 4, lines 39-40 and col. 5, lines 24-27 and 40-44) which means that the measuring area does not conform and will no longer be considered which is reasonably interpreted to be a change in the measuring area performed by the automated microscope system, as stated in instant claims 6 and 11. Wilhelm et al. disclose a performance requirement of scoring no more than 5% of the training slides as being unsuitable (col. 5, lines 24-27), which represents use of more than one slide such that stopping the processing of a slide and proceeding processing with another slide clearly represents a changing in position of the measuring area with

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regard to the biological sample. Wilhelm et al. disclose clinicians using normal detected cells as reference cells against which all other cells on the slide can be compared (col. 5, lines 52-54).

Thus, Wilhelm et al. anticipate the limitations in claims 1-4, 6-9, and 11-14. This rejection is necessitated by amendment.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-15 is necessitated by amendment under 35 U.S.C. 103(a) as being unpatentable over Wilhelm et al. (P/N 5,715,327) in view of Sammack et al. (US 2001/0041347).

The amended claim wording of “entire” regarding the area of the linear structure in amended claims 5, 10, and 15 will not be addressed as this term is considered NEW MATTER and must be removed from the affected claims. The amended claim wording interpreted to require at least a length and at least an entire area of the linear structure in amended claims 5, 10, and 15 will not be addressed as this amending to include both data (via the use of “(i)” and “(ii)”) is considered to be NEW MATTER. (Support in the specification, figures, and claims as originally filed state that either length or area of the linear structure are required, not both).

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Wilhelm et al. describe the limitations of claims 1-4, 6-9, and 11-14 (see 102 (b) rejection above). Wilhelm et al. do not describe the biological sample as a cell having a linear structure extending from a main body of a soma and the numerical data including at least one of a length and an area of the linear structure. One definition of “soma” is cell body that is defined on the online Merriam-Webster Dictionary as the nucleus-containing central part of a neuron exclusive of its axons and dendrites.

Sammack et al. describe automated systems, methods, screens, and software for the analysis of cell spreading via measurements calculated from cell images (abstract). Sammack et al. describe cells that include proteins that label microtubules fused to a luminescent protein. As the Merriam-Webster Dictionary defines microtubules as “any of the minute tubules in eukaryotic cytoplasm that are composed of the protein tubulin and form an important component of the cytoskeleton”, Sammack et al. describe labeled MAP4 (microtubule-associated protein 4) and MAP2 that can serve as an indicator of the localization (area), organization, and integrity of microtubules (linear structures extending from a main body of a soma) (page 30, paragraphs 0333-0334). MAP2 is expressed specifically in neuronal cells (page 30, paragraph 0334) which is reasonably interpreted to be an indicator of the presence (area) of the linear structures of microtubules found in a neuron. In Figure 9, Sammack et al. describe locating an object in a field (110) and if it does not meet valid cell criteria, then the rest of the current field is searched for unprocessed objects (113) which represents a changing of measuring area because previous area did not conform, as stated in instant claims 6 and 11. In Figure 9, if the current plate is not finished (114) then other wells are found (115) and the stage is advanced to the next well (116) which also represents a changing in measuring area, as stated in claims 6 and 11.

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Wilhelm et al. state if a particular slide is anomalous, or if the automated cytology system did not operate effectively on the slide, it would be desirable to flag the unacceptable machine condition or slide characteristic so that potentially false results are not used (col. 1, lines 25-30). Wilhelm et al. state that various modifications could be made to their invention without departing from the scope of the invention (col. 8, lines 31-36). Sammack et al. state their invention is in the field of fluorescence-based cell and molecular biochemical assays for drug discovery (page 1, paragraph 0002). Sammack et al. state that drug discovery is a slow and costly process (page 1, paragraph 0004). Sammack et al. state it is necessary to provide new technologies to rapidly screen disease associated sequences to establish biological function to improve target validation and candidate optimization in drug discovery (page 1, paragraph 0005). Sammack et al. state there is a need to acquire, manage, and search multi-dimensional information from cells (page 1, paragraph 0006). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make improvements to drug discovery techniques of drug targets, as stated by Sammack et al., by automating cytology scoring and eliminating false results, as stated by Wilhelm et al., because this would provide higher throughput tools of extracting multiple parameter information in automated systems, as stated by Sammack et al. (page 1, paragraph 0006). Therefore, it would have been obvious to one of ordinary skill in the art to improve efficiency of cytology automated procedures for determining suitability of slides, as stated by Wilhelm et al. by miniaturizing methods involving nerve cells and other drug targets, as stated by Sammack et al., in order to improve drug discovery with increased throughput while decreasing volumes of reagents and test compounds required in each assay, as stated by Sammack et al. (page 1, paragraph 0006).

Thus, Wilhelm et al., in view of Sammack et al., motivate the claims in the instant invention. This rejection is necessitated by amendment.

Applicant states that the instant invention recites an evaluation apparatus having a measuring area changing unit for changing position of a measuring area with regard to a biological sample when a condition pass/fail determining unit determines a predetermined condition is not met. This statement is found unpersuasive as noted above:

Wilhelm et al. disclose the apparatus includes an imaging system, a motion control system (measuring area changing unit), an image processing system (condition determining unit and digitizing unit), a central processing system, and a workstation (col. 3, lines 49-52 and col. 4, lines 23-26 and 37-42). Wilhelm et al. disclose the motor drivers position the slide under the optics (col. 4, line 9) and that measurements are taken on requested fields of view (col. 1, lines 17-18) so that the motor driver is reasonably interpreted to be a measuring changing unit that changes the measuring area, as stated in instant claim 1. Wilhelm et al. disclose a slide must pass all tests in order to be suitable for reporting results (col. 4, lines 39-40) which represents acquisition of data judged to conform to the condition, as stated in claims 6 and 11. Therefore, if a slide does not pass all tests, then processing is considered unsuitable and result processing must cease (col. 4, lines 39-40 and col. 5, lines 24-27 and 40-44) which means that the measuring area does not conform and will no longer be considered which is reasonably interpreted to be a change in the measuring area performed by the automated microscope system, as stated in instant claims 6 and 11. Wilhelm et al. disclose a performance requirement of scoring no more than 5% of the training slides as being unsuitable (col. 5, lines 24-27), which represents use of more than one slide such that stopping the processing of a slide and proceeding processing with another slide clearly represents a changing in position of the measuring area with regard to the biological sample.

Applicant notes differences between the instant invention versus the Wilhelm et al. and Sammack et al. inventions, such as changing a position of a measuring area. The broad limitation of position changing is included in the Wilhelm et al. reference as described in the paragraph above. While the inventions are not exactly the same, instant claims are reasonably and broadly interpreted to encompass the Wilhelm et al. and Sammack et al. inventions.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

June 15, 2004

Ardin H. Marschel 6/23/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER